

Final Progress Report

Title of Project: Optimizing safety of mother and neonate in a mixed methods learning laboratory

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OVERVIEW

Purpose and Scope

Although the U.S. healthcare system employs the most advanced medical technologies utilized by well-trained healthcare professionals (HCPs) and spends the most money per capita in comparison with other developed countries, it nevertheless performs poorly in many indicators of overall health quality. This gap in quality is particularly prominent in the area of perinatal health, such that the U.S infant mortality rate is three times that of nations such as Iceland, Finland, and Japan, and severe maternal morbidity has risen over 200 percent from 1993-2014 based on CDC estimates.

Specific Aims and Projects

To address these issues, we established a safety learning laboratory that carried out four key projects to optimize neonatal and maternal safety immediately prior to, during, and after delivery. Those projects are:

- 1) An Optimal Data Display for Neonatal Resuscitation
- 2) An Optimal Data Display for Labor and Delivery (L&D)
- 3) Improving Recognition of Maternal Clinical Deterioration
- 4) Physical Design of the Optimal Delivery Suite

Our first aim was to study how the flow of communication impacts patient safety. This encompasses information received by HCPs from data displays, medical devices, other clinicians, and patients. In projects 1 and 2, we prototyped and tested new displays that communicate key data to the HCPs delivering care to newborns and mothers during labor and delivery. The goal of project 3 was to determine factors that hinder timely identification and mitigation of maternal clinical deterioration and to develop and evaluate strategies for addressing these concerns.

Our second aim was to study how physical design elements may impact patient safety. Under project 4, we conducted site visits of 10 L&D units across California to evaluate how the physical layout and organization of spaces impact patient safety. We also considered the micro-components of physical design by prototyping two devices to improve patient safety: the delayed cord clamping cart (DCCC) and the pelvic lift cushion (PLC).

Our third aim was to develop a systematic approach to studying patient safety using qualitative research, implementation science, simulation, and clinical research design. As a multidisciplinary group of HCPs, designers, and engineers, we utilized the process of problem analysis, design, development, implementation and evaluation in all four projects. All the projects began with focus group interviews and observations as part of the problem analysis phase before proceeding to iterative design and testing.

Outcomes

Numerous important outcomes were achieved. **First**, the concepts and devices generated by our team during the grant period serve to advance the science of safety in communication. Identification of communication barriers in project 3 led to a safety culture initiative to improve teamwork between nurses and physicians in L&D at the University of California San Francisco Medical Center. The data displays developed in projects 1 and 2 and the physical design ideas generated in project 4 all incorporated methods of improved communication. **Second**, we developed a methodology to test aspects of patient safety across clinical fields. As a multidisciplinary group, we brought diverse perspectives from the areas of neonatology, obstetrics, anesthesiology, nursing, design, engineering, and architecture when creating and testing solutions for patient safety. **Third**, we created innovative devices that hold great potential to improve maternal and neonatal care while lowering the cost of that care. For example, commercialization of the PLC will enhance the quality and reduce the cost of pelvic exams in low-resource settings. The toolkit developed in project 3 will mitigate or prevent many cases of clinical maternal deterioration, thereby reducing the burden of disease. Our recommendations for optimizing the layout of L&D for patient safety will serve as a guidepost for architects designing new hospital spaces and the patients who will utilize them.

The following report highlights in detail the methodologies and results of our four projects and the corresponding sub-projects.

PROJECT 1: AN OPTIMAL DATA DISPLAY FOR NEONATAL RESUSCITATION

Project 1a: Optimizing technical performance through gaze pattern categorization during simulated neonatal resuscitation

Abstract

Purpose: We sought to examine the association between technical performance and gaze pattern during simulated neonatal resuscitations among HCPs.

Scope: Neonatal resuscitation teams have to perceive and process a significant number of data streams to provide care, which may increase the leaders' cognitive workloads, decrease situation awareness, and degrade performance. Eye tracking studies in non-healthcare industries have shown that inexperienced subjects can be trained to exhibit more organized gaze patterns that are similar to those of experts in their fields. Similar work has not been performed in the field of resuscitation.

Methods: A prospective observational study involving 13 HCPs was conducted to examine gaze patterns and performance during simulated neonatal resuscitation. The gaze patterns of subjects were analyzed using a Tobii Pro 2 eye tracking system. Fixation was defined as steady gaze in an area of interest (AOI) for at least 33 ms. Each subject's technical performance was rated over four scenarios. Scenarios 1-3 were "hands OFF," in which the subject was asked to step back and not perform procedures. Scenario 4 was "hands ON" (subjects performed technical procedures themselves).

Results: The most common fixation point was on the HCPs assisting the subject with resuscitation during all scenarios and at every level of technical performance. Subjects with the highest-rated technical performance over four scenarios spent significantly more time fixating on the assistants and less time focused on the heart rate (HR)/SpO₂ monitor. There is an association between gaze pattern and technical performance during simulated neonatal resuscitation.

Key words: data display, neonatal resuscitation, eye tracking, gaze tracking

Report

Purpose: We sought to determine whether HCPs acting as the team leader during simulated neonatal resuscitation would exhibit gaze pattern characteristics that can be correlated with their degree of technical performance.

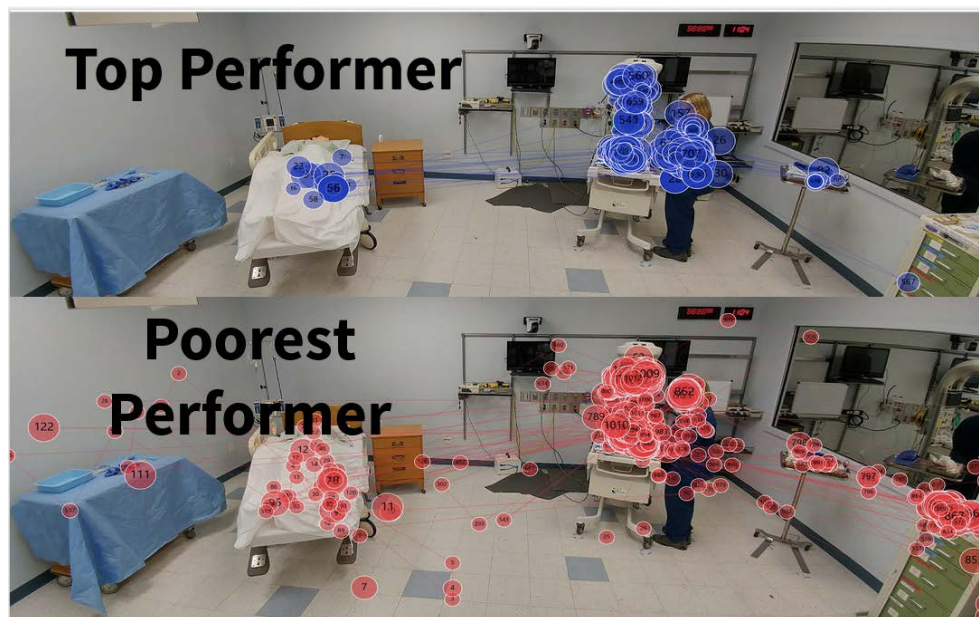
Scope: Neonatal resuscitation teams have a significant number of data streams to perceive, comprehend, process, and act upon to provide safe, efficient, and effective patient care. Each of these data streams represents the potential to increase the leader's cognitive workload, decrease their situation awareness, and lead to fixation errors that degrade team performance. Eye tracking has been used in aviation and surgery, revealing that (1) novices and experts have different gaze patterns, (2) more organized gaze patterns correlate with improved technical performance, and (3) novices can be trained to have more organized gaze patterns. When this technology was applied in aviation, it was noted that more experienced pilots had a tighter gaze pattern, slower eye scanning, decreased fixation errors, improved situation awareness, and decreased cognitive workload. Similar work has not been performed to describe the characteristics of a team leader's gaze pattern during resuscitation that lead to optimal technical performance.

Methods: This is a prospective observational study examining gaze patterns and performance during simulated neonatal resuscitation; 13 HCPs holding current Neonatal Resuscitation Program (NRP) Provider status who regularly attend deliveries were recruited. Subjects' gaze patterns were documented with a Tobii Pro 2 eye tracking system, and technical performance was recorded on digital video. Each subject acted as team leader during four standardized resuscitation scenarios of fixed duration. Each simulated patient had a heart rate <60 and apnea throughout the scenario in order to promote progression through the NRP algorithm and elicit increased cognitive demands. In Scenarios 1 to 3, subjects were "hands OFF" – they were asked to step back and not perform procedures. In Scenario 4, they were "hands ON" and performed procedures themselves. Thirty-three recorded resuscitations were analyzed. Potential AOIs included assistants, HR/SpO₂ monitor, Apgar timer, FiO₂/pressure controls, mother delivering, and the neonate. Fixation was defined as steady gaze in an AOI for at least 33 ms. Each subject's technical performance was rated over four scenarios.

Results:

Principal findings: For all scenarios across technical performance ranges (n=33 videos, 13 subjects), the most common first fixation point was on the assistants (42%). Most subjects spent the majority of time fixating on the simulated patient (n=33, 86% of subjects). When the team leader was hands ON vs. hands OFF, he/she spent more time fixating in each area [2104 ms (STD 398) > 1244 ms (STD 408); $p < 0.001$]. When the team leader was hands OFF, he/she looked at the assistants more often [15.1 (4.5) vs. 9.9 (5.4); $p = 0.023$] and, alternatively, checked pressure/FiO₂ more frequently when they were hands ON [20.1 (5) vs. 11.7 (5.4); $p = 0.024$]. Subjects with the best technical performance over all four scenarios spent significantly more time fixating on the assistants and less time focused on the HR/SpO₂ monitor.

Conclusion: During simulated neonatal resuscitation, team leaders spent the majority of time fixating on the patient and assistants. However, when team leaders were performing procedures, they looked more frequently at FiO₂/pressure controls and spent a longer duration of time per fixation. Hence, team leaders may be more likely to exhibit fixation errors and decreased situation awareness when performing procedures themselves. Additionally, there are significant differences in gaze patterns between those who had the best and worst technical performances (see image that follows).



Project 1b: Optimizing hemoglobin-oxygen saturation monitoring (SpO₂) to aid decision making during simulated neonatal resuscitation

Abstract

Purpose: We sought to determine how the introduction of a novel data display with target SpO₂ ranges (desired SpO₂ by minute after birth) affects visual attention, gaze patterns, and decision making for team leaders during simulated neonatal resuscitation.

Scope: During neonatal resuscitation, oxygen is titrated to achieve targeted oxygen saturations (SpO₂) on a minute-by-minute basis. Because the target range changes over time, HCPs must maintain situation awareness of SpO₂, FiO₂, elapsed time, all interventions, and overall patient status on a continuous basis. This results in significant mental workload for HCPs conducting neonatal resuscitation.

Methods: We developed a novel display that indicates HR, SpO₂, a graph of the desired SpO₂ range over time, and elapsed time. In a prospective, randomized, controlled crossover study, we compared the performance of HCPs leading simulated neonatal resuscitation using this novel display and a standard vital sign display (HR and SpO₂ only). Subjects included 11 nurses and 11 physicians with varying levels of experience.

Each subject participated in four simulated scenarios: easy with control display, difficult with control display, easy with novel display, hard with novel display.

Results: The mean duration in SpO₂ target ranges differed by experience level. Level of training and cognitive workload affect visual attention patterns, HCP performance, and use of the displays. Prior training is crucial for effective use of the novel display, particularly when users encounter a high cognitive workload.

Key words: data displays, neonatal resuscitation, eye tracking

Report

Purpose: We sought to determine how the introduction of a data display with appropriate SpO₂ ranges affects visual attention and decision-making of resuscitation team leaders.

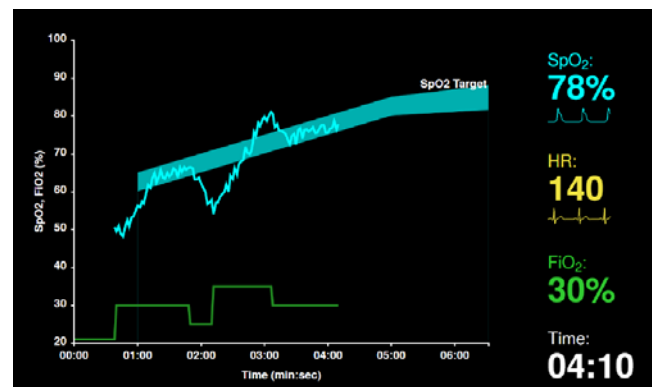
Scope: During neonatal resuscitation, oxygen is titrated to achieve targeted SpO₂ values for the first 10 minutes of life, as specified by NRP guidelines (see table that follows).¹ This task is challenging for HCPs, who must maintain situation awareness of SpO₂, FiO₂, elapsed time, all interventions, and overall patient status on a continuous basis.

Target pre-ductal SpO ₂ after birth	
1 min	60%-65%
2 min	65%-70%
3 min	70%-75%
4 min	75%-80%
5 min	80%-85%
10 min	85%-95%

Methods: To address this issue, we developed a novel neonatal display that indicates HR, SpO₂, a graph of the desired SpO₂ range over time (target SpO₂ range/unit time is highlighted), and elapsed time. In a prospective, randomized, controlled crossover study, we compared the performance of HCPs leading simulated neonatal resuscitation using this novel display and a standard vital sign display (HR and SpO₂ only). Subjects included 11 nurses and 11 physicians with varying levels of experience. Each subject participated in four simulated scenarios: easy with control display, difficult with control display, easy with novel display, difficult with novel display.



Standard/Control Display



Novel Display

For each pair of scenarios, one scenario used the standard display, and the other scenario used the novel display; the order of displays was randomized for each scenario pair and each subject. Subjects wore an eye tracking system to record their gaze pattern and fixation, and all treatment decision events and vital signs were logged. The principal outcome of interest was duration of time spent within the SpO₂ target range. Gaze pattern and fixation measurements included but were not limited to duration of visual attention on the SpO₂ number and the total time spent viewing the patient, monitor, and Apgar timer. Measures for treatment decision events included time to a) adjust the FiO₂ to achieve goal SpO₂, b) start PPV, and c) appropriately use CPAP as well as total time within the FiO₂ goal.

The experience level assigned to subjects was based on total experience (cumulative number of years working in the NICU) and recent experience (number of resuscitations led in the past year).

Results: The highest possible duration in SpO₂ target range was 180 seconds. The highest measured duration was 120 seconds in the easy scenario and 90 seconds in the difficult scenario. Mean duration in SpO₂ target range differed between subjects with no resuscitation experience in the past year versus those who with recent experience (23 vs. 47 seconds [$p<0.001$]). Results were similar when stratified by easy or difficult scenario types and among other measures of experience. Mean durations in SpO₂ target range were 10 seconds for easy scenarios and 54 seconds for difficult ones ($p<0.001$). In easy scenarios, subjects spent on average 11 seconds longer in the SpO₂ target range when using the novel display compared with use of the standard display ($p=0.095$). In difficult scenarios, subjects spent on average 10 seconds longer in the SpO₂ target range when using the standard display versus the novel display ($p=0.072$). When stratifying recent experience and scenarios, we found that the novel display produces significant improvements only for those with more recent experience (>0 resuscitations led in the past year) during easy scenarios; those with more recent experience spent on average 25 seconds more time in the desired SpO₂ range than others when using the novel display ($p=0.015$). With regard to visual attention, we found that subjects gazed longer at the SpO₂ number with the standard display ($p=0.088$) and SpO₂-related information ($p=0.007$) on the novel display.

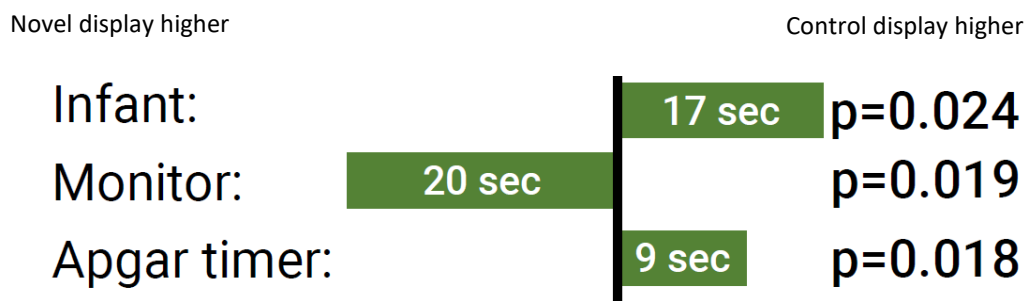


Figure. Mean difference in durations of visual attention between control/novel displays among subjects with more recent experience during difficult scenarios.

Conclusion: This study suggests that level of training and cognitive workload affect visual attention patterns, performance, and use of data displays. The results also indicate that prior training is crucial for effective use of the novel display, particularly when users encounter a high cognitive workload. Introducing a novel visual SpO₂ targeting system may not by itself improve decision making regarding oxygen supplementation; rather, other factors, such as prior experience and training, may be strong determinants of the benefit of such a system.

References

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PROJECT 2: AN OPTIMAL DATA DISPLAY FOR LABOR AND DELIVERY

Abstract

Purpose: We sought to develop a data display that improves the performance of HCPs caring for a decompensating obstetric patient.

Scope: A routine delivery can rapidly become a high-risk situation for both mother and baby, requiring immediate recognition and action on the part of both the obstetric and pediatric teams. The display of accurate real-time information offered by a clinical support tool (CST), integrated with the electronic medical record (EMR), has the potential to enhance perinatal safety.

Methods: Focus group interviews, observation of simulated obstetric scenarios, and consultation with user interface designers and EMR experts were employed to design an obstetric data display.

An EMR was integrated into the visual display, providing the end user with real-time data and an interactive clinical care checklist. Usability testing in a simulated setting was then performed in an iterative process to optimize the prototype.

Results: The novel data display was highly endorsed by HCPs. The availability of dynamic data obtained via the EMR along with the addition of a clinical checklist was deemed to be of great benefit by HCPs using the display. Challenges with integration of the EMR were encountered; certain pertinent data could not be automatically updated via EMR and required manual input. Early collaboration with a multidisciplinary HCP team and consultation with experts in human factors, engineering, and EMRs are crucial to identifying pertinent data and designing a clinically useful data display.

Keywords: EMR, labor and delivery, data display, communication, user-interface design, iterative testing, cognitive aid, checklist, clinical support tool.

Report

Purpose: We sought to develop a data display that improves the performance of HCPs caring for a decompensating obstetric patient.

Scope: The delivery room is a busy environment with teams of obstetricians, anesthesiologists, pediatricians and nurses often caring for two potentially critically ill patients in the same physical environment. The availability of real-time, pertinent data and cognitive aids (such as a procedure checklist) has the potential to improve maternal patient safety. Although numerous checklists for obstetric emergencies exist, such checklists may not be utilized at the time of an emergency if they are not readily available or are inconsistently used. Thus, it is important to integrate a checklist that could not only be easily updated as the emergency evolves but also could be used as a CST. To address this issue, we focused on development of a novel maternal data display that also incorporates a clinical checklist.

Methods: Focus group interviews were used to identify critical patient information at the time of an obstetrical emergency. We then reviewed videotaped simulated obstetrical emergencies involving a multidisciplinary team of obstetricians, anesthesiologists, pediatricians, and nurses and evaluated the most commonly asked questions from each team member (see table that follows).¹ Finally, the prototype display was used during simulated obstetric crises to generate usability data; this set of data was then used to make iterative modifications to improve the overall functionality of the display.

Results: Information obtained from focus groups conducted with HCPs and additional input obtained from user interface designers and EMR experts aided initial design of the prototype. Review of simulated obstetric crises indicated that the questions listed in the following table were the most frequently asked.

Question	Postpartum hemorrhage scenario	
	Percent of simulations when question asked	Percent when question repeated
Has someone called anesthesia?	78%	43%
Do you have an epidural?	67%	17%
Is the placenta still in?	67%	33%
What's the estimated blood loss (EBL)?	56%	20%
How long ago was the child born?	56%	40%
Have we called for a postpartum hemorrhage kit?	56%	60%

This information drove initial design, resulting in the following features being incorporated into the display prototype: a) patient data deemed critical during an obstetrical emergency, b) decision support checklists, c) the ability for HCPs to directly input dynamic information, and d) relevance during non-emergent scenarios as well (Figure 1). The EMR designers set realistic expectations about the content that could be included in the display, and the user interface designers provided suggestions on the optimal design, size, layout, color, and location of the display in the room. Integrating our EMR system was vital, because it prevented duplicative processes and simplified workload; provided real time automated patient information; facilitated familiarity with the display and thereby reduced the need for training; and archived critical time events in one record system. Although collaboration with EMR designers was essential to the development process, the timeline of development and implementation was delayed, because EMR designers were funded by the hospital and were also involved in numerous other projects, limiting their availability. In addition, there were other limitations within the EMR, including the presence of automated extraneous data (e.g., long medication lists, non-relevant medical history), an inability to create visual graphs or figures of patient data initially proposed by the human factors designers, and an inability to automatically update all pertinent data that then necessitated manual input of key variables (such as estimated blood loss and transfusion products). We also encountered challenges with the location, placement, and size of the display due to safety regulations and weight limitations.

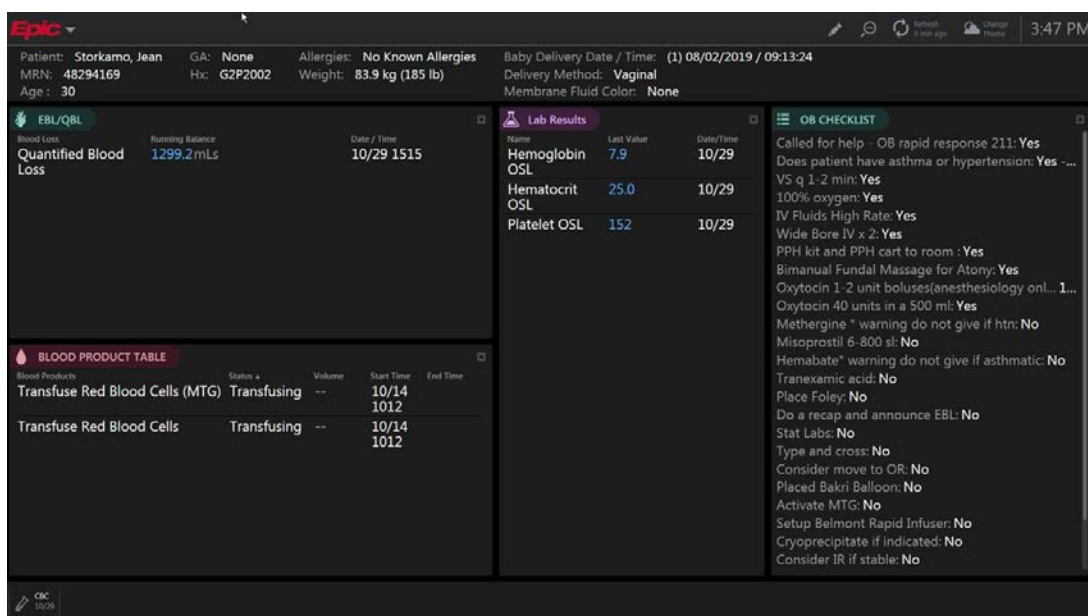


Figure 1: Visual display integrated with EMR and decision support checklist.

Conclusion: Early collaboration with a multidisciplinary team of HCPs is crucial to identifying the data that are most pertinent to clinical care. Consultation with experts in human factors, engineering, and EMRs is also important. Successful implementation of a new data display is also aided by its placement in the same location as the previous display (achieves location familiarity). Regular use is encouraged if a novel display can be used during routine, urgent, and emergent situations.

References

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PROJECT 3: IMPROVING RECOGNITION OF MATERNAL CLINICAL DETERIORATION

Abstract

Purpose: We sought to determine factors that may hinder timely identification and mitigation of maternal clinical deterioration and to develop and evaluate a strategy to address these factors.

Scope: The CDC estimates that at least 700 women die annually in the U.S. from complications of pregnancy and birth. Severe maternal morbidity has risen over 200 percent from 1993-2014 and affects at least 50,000 women annually. The CDC and other estimates suggest that maternal mortality and severe maternal morbidity are highly preventable; thus, investigation of contributing factors and support for identifying and mitigating progression to morbidity and death are needed to improve maternal safety.

Methods: This descriptive study used clinician surveys, interviews, ethnographic observation, and patient chart review in an academic medical center to identify clinical triggers that can be applied to safety models for obstetrics. In total, 184 HCPs participated, 112 patient cases were reviewed, and 17 women were interviewed about the meaning of safety in childbirth.

Results: Barriers to recognition and mitigation included poor communication, clinical complexity, disruptive environmental changes, and suboptimal nurse and physician staffing. Indeterminate and abnormal fetal heart rate tracings and clinical complexity (especially hypertensive disorders and preterm labor) were markers of potential maternal clinical deterioration. Adaptation of robust planning models to suit specific environments and teamwork training are necessary to effectively implement safety improvements. The impact of unit layout and integration of technology may need additional consideration in hospital design and remodeling.

Key words: communication; clinical deterioration; maternal safety; safety culture

Report

Purpose: We sought to determine factors that may hinder timely identification and mitigation of maternal clinical deterioration and to develop and evaluate a strategy for improving identification and mitigation in clinical settings.

Scope:

Background, context, and prevalence: The CDC estimates that at least 700 women die annually from complications of pregnancy and birth. Severe maternal morbidity has risen over 200 percent from 1993-2014 and affects at least 50,000 women annually. The CDC also estimates that 60 percent of maternal deaths may be preventable, and reviews of severe maternal morbidity also suggest that a substantial proportion may be preventable. Labor and delivery present special challenges for HCPs attempting to maintain situation awareness. On the one hand, labor is a natural process that will progress without incident in the most healthy women. On the other hand, the potential for sudden, catastrophic complications such as umbilical cord prolapse, uterine rupture, and massive hemorrhage is ever present. Maintaining readiness to respond to these emergencies without over-treating normal labor is an ongoing challenge. Human factors and systems issues are consistently identified as contributory to preventable morbidity and death. Thus, additional strategies for identifying and mitigating progression to morbidity and death are needed.

Methods: This was a descriptive study design structured on a design thinking process. The problem analysis included evaluation of whether or not the triggers outlined in Brady's model for robust planning (developed in a pediatric population) were applicable to the birth setting. Interviews with physicians and nurses explored barriers and facilitators to recognition and mitigation of clinical deterioration. A safety culture survey was conducted to track changes over time. Data sources included chart reviews of 112 patients whose cases met facility criteria for morbidity and mortality review, 100 hours of unit-based observation (weekly morbidity and mortality review, staff meetings, rounds, and shadowing individual physicians and nurses), individual interviews with physicians and nurses, small group interviews with nurses, a survey of birth center staff, and individual and small group interviews with women recruited by a parent advisor at a different birth center. Qualitative data were analyzed using grounded theory and thematic analysis. Survey measures included the SAQ teamwork and safety climate scales, quality of communication and collaboration questions, a disruptive behavior scale, and the likelihood of speaking up scale.

The study setting was an inpatient birth center (encompassing labor and delivery, antepartum, postpartum, triage, operating room, and postoperative recovery) located in a tertiary/quaternary academic medical center children's hospital. The birth center moved to a new hospital and increased birth volume by 37 percent during the study period. Subjects included 112 patients (by chart review), 17 women with a previous birth, and 184 clinical staff. Clinical staff participation comprised 160 safety survey participants (18 obstetric faculty, five anesthesia faculty, 14 obstetric medical residents, four nurse practitioners, 97 registered nurses, five ancillary staff, and 17 participants who did not specify their role) and 24 interview participants (11 physicians and 13 nurses).

Results: Principal findings from the chart review indicated that most of the five triggers proposed by Brady (abnormal vital signs, “watcher” status, high-risk medications, communication problems, family concerns) were applicable to the inpatient obstetric population, but additional factors needed to be considered (see table that follows).

Triggers present on chart review	
Type	Number of cases (%)
Category II (indeterminate) or III (abnormal) fetal heart rate tracing	80 (71%)
Abnormal vital signs	65 (58%)
35 hypertension	
16 hypotension	
14 elevated temperature and maternal tachycardia	
“Watcher” status	39 (35%)
Other	36 (32%)
chorioamnionitis	
declined recommended treatment	
headache/severe features with hypertension	
placental abnormality	
prematurity	
High-risk/unfamiliar medications ^a	31 (28%)
25 magnesium sulfate	
3 insulin drip	
4 remifentanyl	
Communication problems	15 (13%)
3 language barrier	
9 RN notes indicative	
2 coordination between services	
Family concerns ^b	8 (7%)
^a Oxytocin is a high-risk medication commonly used in obstetric care. We did not include this in our high-risk/unfamiliar medication group.	
^b Family concerns were variable and not well captured in chart notes.	

Our a priori assumption that fetal heart rate changes would be present in cases with morbidity was confirmed. We found that communication problems and family concerns were difficult to identify via record review. Chart review, interviews, and observation revealed that communication problems were often present, though family concerns were less so. We also identified clinical complexity (especially hypertensive disorders with severe features and prematurity) as a factor to be taken into account in an obstetric trigger model. Evolution of the fetal heart rate tracing over time presented challenges to recognition, and hypertensive disorders and prematurity sometimes presented challenges to mitigation, as the benefits of both working to extend the pregnancy and working to expedite birth often required balancing maternal and fetal risks.

Interviews and observations revealed problems with interprofessional communication and, at times, lack of accurate knowledge regarding the physiologic significance of abnormal vital signs. Though the clinical setting was enthusiastic in principle about piloting a robust planning model, we were unable to implement this due to a series of other higher-priority initiatives taking place during the life of the project, including a move to a new campus, adoption of new state-level performance standards adversely affecting obstetric reimbursement if not met, and a high level of leadership turnover (department chair, unit director, multiple physicians, nurse manager, clinical nurse specialist).

Other unexpected barriers to recognition of clinical deterioration included geography and technology. Despite extensive planning in advance of the move, including “Day in the Life” in situ drills in the new hospital for all physicians and staff, the move to the new facility was profoundly disruptive. Clinicians found the new spread-out geography difficult to navigate and a barrier to maintaining situation awareness, as they no longer had a central hub where antepartum, intrapartum, and perioperative care were collated in very close proximity. A new phone-based communication technology was also difficult to navigate, particularly for nurses tracking changing physician teams over time. These problems eventually resolved as people acclimated to the new environment and worked out technological challenges. However, some concerns about responsiveness of consulting services and technologies persist. Further exploration of family concerns was taken in a qualitative exploratory study of women’s perceptions of safety during childbirth. Seventeen women aged 29-47 participated in interviews about their birth experiences. We found that feelings of physical and emotional safety are embedded in the overall patient experience, which is affected by interpersonal relationships, environmental factors, and organizational factors. Women highly valued human connection from clinicians, especially in what we called “risk moments” or times of rapid change. At these times, the physical environment and team interactions could be particularly overwhelming.

Conclusion: The setting for this study was unlike the majority of birth hospitals; however, this setting offered greater opportunity for observation and discussion of highly complex cases, revealing somewhat unexpected findings that can be considered for incorporation into safety models for recognition and mitigation of maternal clinical deterioration. Communication and teamwork breakdowns continue to present barriers to mitigation of clinical deterioration and contribute to other factors in ways that can be difficult to trace from chart review. From the patient’s perspective, safety during labor and birth is inextricably linked to factors that are often considered “patient experience” rather than “safety.” There likely will need to be adaptation of robust planning models to suit specific environments, and teamwork training is foundational to implementing safety improvements. Moving campuses was highly disruptive, and changing the physical plant was disorienting to HCPs in unexpected ways. The impact of unit layout and integration of technology may need additional consideration either in hospital design or in developing transition plans for new or largely remodeled facilities.

PROJECT 4: PHYSICAL DESIGN OF THE OPTIMAL LABOR AND DELIVERY SUITE

Project 4a: Physical design site visits

Abstract

Purpose: We sought to determine the “standard” dimensions of L&D units and whether there is any correlation between these physical characteristics and clinical outcomes.

Scope: Design standardization, while common in other high-stakes industries such as aviation and aerospace, is not routine practice in healthcare. There is limited research exploring the relationship between the physical design of labor and delivery units and patient safety and clinical outcomes.

Methods: A multidisciplinary team conducted site visits at 10 California hospitals, where they collected data through measurements, observations, and interviews. We assessed the physical characteristics of these units and correlated space measurements with clinical outcomes. We also used design thinking methodology to identify areas of hospital design that impact patient safety, care, and workflow.

Results: Tremendous heterogeneity exists in labor and delivery unit design, and that correlates with delivery volumes and cesarean section rates. Specifically, there was significant heterogeneity in labor room (LR) and operating room (OR) size, count, and number of configurations. Of note, there was significant homogeneity of equipment.

Delivery volumes correlated with unit size, room counts, and cesarean delivery rates. Relative risk of cesarean section varied somewhat based on design. Hospital building codes ensure general safety but do not account for workflow, human factors, and user experience. Using design thinking methodology, we defined three areas in need of improvement: a) availability of blood for hemorrhage; b) appropriate space for neonatal resuscitation; and c) restocking and organization methods of equipment and supplies.

Key words: obstetrics, neonatology, hospital design, standardization, design thinking methodology.

Report

Purpose: We sought to evaluate how the physical layout of L&D units may impact patient safety and clinical outcomes through site visits.

Scope: Giving birth is the most common reason for hospital admission in the U.S.¹ Despite advances in obstetric care, the peripartum period represents a high-risk situation for both pregnant patients and neonates. Patients may be placed at risk because of environmental factors, such as physical space, resources, protocols, or culture.^{2,3} How the design of hospital spaces contributes to safety and clinical outcomes is not well defined.

Patient care on L&D is complex and presents several design challenges. An optimally designed unit would maximize safety and efficiency and readily accommodate the unpredictable timing and sudden surges in acuity and volume inherent to obstetric medicine. Yet, designs are subject to multiple influences, such as building codes, available guidelines,⁴⁻⁸ budget constraints, and input from various stakeholders (i.e., architects, builders, engineers, executives, clinicians, and patients). HCPs and patients who work and are cared for in L&D units have variable (often minimal) involvement with managers, executives, and other professionals responsible for designing such units.

Though design standardization is the norm in environments as diverse as airline cockpits and kitchens, it is less commonly applied to healthcare settings. Healthcare arguably is behind other industries in devising guidelines on physical design aimed to improve safety and clinical outcomes. The impact of physical design on outcomes in L&D is of growing interest,^{9,10} as it appears that factors related to the facility itself may play an important role in patient safety.^{11,12} Design thinking methodology can help us better understand the L&D environment and identify areas in need of improvement and standardization. Design thinking takes a human-centered approach to solving problems and is chiefly concerned with end users, who in medicine are both HCPs and patients.

Methods: To begin to address gaps in our understanding of how physical space design contributes to safety and clinical outcomes, we organized site visits of 10 L&D units in California hospitals. This observational study included both quantitative and qualitative components.

Quantitative: We accessed hospital building plans, measured spaces, and inventoried and measured equipment in each unit in order to determine variability in design among hospitals. We correlated measurements with delivery volumes and basic clinical outcomes of vaginal and cesarean birth.

Qualitative: By interviewing staff and observing staff in the L&D unit space, we employed design thinking methodology to understand the L&D environment at each hospital. Through this understanding, we were able to determine the prevalence of human-centered design and identify areas of design in need of improvement. During the same time period in which we conducted the site visits, we aimed to acquire a basic understanding of how hospitals are constructed and designed. We spoke with individuals with knowledge of building codes and hospital design. These unstructured discussions were intended to give the site visits context and provide us with a more comprehensive understanding of the top-down factors that influence hospital design---namely, building codes and hospital construction guidelines.

Participating L&D units were located in academic and private hospitals throughout California. We invited 13 units to participate, and we toured the first 10 that accepted our invitation between July 2015 and February 2017. A multidisciplinary team of physicians (obstetrics, maternal-fetal medicine, pediatrics, and neonatology), nurses and experts in design, engineering, architecture, and human factors conducted the site visits. With the assistance of HCPs at each institution, members of our team toured facilities and acquired direct measurements of labor rooms, operating rooms, and other areas as well as equipment within the rooms. Direct measurements and photographs were combined with facility architectural maps and evaluated with computer-aided design software (Dassault Systemes, SolidWorks Corporation, Waltham, MA) to maximize accuracy.

Current physical design measurements were then evaluated in the context of 2015 hospital delivery data from the California Maternal Quality Care Collaborative. Data were analyzed using SAS v24. Materials and data were stored on a secure platform. Observations were shared and discussed among team members and also with other participating members of our lab at regular meetings. This dialogue informed subsequent site visits and the synthesis of key ideas for this study.

We used design thinking methodology to assess a) the overall L&D unit, b) individual patient rooms (e.g., labor, operating, antepartum, and postpartum), c) staff working areas, and d) other areas (e.g., break rooms, locker rooms, storage). Data were obtained through observations, photographs, tours, and interviews with HCPs. On average, we spoke to three HCPs per hospital. At each unit, we interviewed the physicians and/or nurses in leadership roles who led the tour. We also interviewed a convenience sample of on-duty HCPs. We made formal quantitative measurements, but we made the decision to keep our qualitative observations open ended, unstructured, and observational; therefore, we did not follow formal interview guides. In addition to our site visits, we also interviewed individuals with knowledge of building codes and hospital design, following no formal interview guides during these discussions, either.

Results:

Principal Quantitative Findings & Outcomes: Design measurements were analyzed with California Maternal Quality Care Collaborative (CMQCC) data from a combined 34,161 deliveries at the 10 participating units. The hospitals ranged in delivery volumes (<1000 to >5000 annual deliveries) and cesarean section rates (19.6% to 39.7%). Within and among units, there was significant heterogeneity in LR and OR size, count, and number of configurations. There was significant homogeneity of room equipment. Delivery volumes correlated with unit size, room counts, and cesarean delivery rates. Relative risk of cesarean section was modestly increased when certain variables were above average (delivery volume, unit size, LR count, OR count, OR configuration count, LR to OR distance, unit utilization) or below average (LR size, OR size, LR configuration count).

Principal Qualitative Findings & Outcomes: Designs of L&D units are heterogeneous, lacking in consistency regarding environmental factors that may impact safety and outcomes. Building codes do not take into consideration workflow, human factors, and patient and clinician experiences. Attitudes of hospital staff may contribute to improving safety through design. Three areas in need of improvement and actionable through design emerged: a) blood availability for hemorrhage management, b) appropriate space for neonatal resuscitation, and c) restocking and organization methods of equipment and supplies.

After an Institute of Medicine results 2000 report, “To Err is Human,” there was a substantial increase in the number of patient-safety publications, with the most frequent subject of study being organizational culture.^{13,14} Indeed, our site visits confirmed that attitude matters and organizational culture impacts the physical work environment and clinician experience. Successful design changes come from a culture of inclusion in which every voice matters and buy-in from all users decreases psychological barriers to innovation. We found examples of champions who were able to lead critical thought processes, create prototypes, and test ideas to improve the L&D environment.

As a supplement to our site visits, we also met with members of the Facilities Guidelines Institute, an independent, not-for-profit organization that provides guidance for planning, design, and construction of hospitals. The FGI releases Guidelines for Design and Construction of Hospitals and Outpatient Facilities, and the most recent edition came out in 2018.¹⁵ In 2014, safety risk assessments were incorporated into FGI's Guidelines for Design and Construction of Health Care Facilities, recognizing a need to foster a more proactive approach to patient and clinician safety that takes into consideration environmental factors.¹⁶

The stakeholders whom we interviewed spoke about frequently changing building codes that ensure basic human safety measures but that do not emphasize workflow, human-centered design, or efficiency. Units are built to meet current codes and have fixed floor plans with little flexibility to accommodate changing equipment and long-term fluctuations in patient volume. In many older units, retrofitting and/or remodeling may be needed; however, there are no specific recommendations for environmental improvements. Moreover, space and financial limitations often hinder renovation plans. Our observations revealed many problems that could be addressed with design thinking and standardization.

Of note, in the spring of 2019, we began working with architect Felicia Cleper-Borkovi, a Principal of Arup Group, San Francisco, to design parametric models that represent the L&D of the future. These designs have been informed by our research, and members of the multidisciplinary team have offered feedback on each design iteration. Rather than prescribing a single gold standard design, our goal is to create a library of designs so that hospitals can pick and choose what works best for them.

Limitations to this study included the following:

- a) We did not link a unit's space, configuration and equipment usage to other important factors, such as staffing requirements, in-depth clinical outcomes, or maternal/neonatal level of care.
- b) We were only able to speak with the HCPs who were available during our site visit.
- c) We did not observe or speak with patients.
- d) Our multidisciplinary team may have been biased in the questions that we asked during interviews.
- e) Because we prioritized patient privacy, we did not audio record interviews with HCPs, relying instead on notes and team discussions; therefore, we were unable to formally analyze interviews using traditional qualitative methodologies.

Conclusion: The 10 California L&D units included in this observational study varied in size and delivery volume. By no means exhaustive, our exploration showed heterogeneity within and among units and inconsistent consideration for human factors. The existing variation that we observed within and among units suggests a gold standard design has yet to be adopted for the L&D environment. A design-centered approach identified opportunities for standardization: a) L&D unit size, b) room counts based on current or projected delivery volume, and c) LR and OR size and equipment. When combined with human factors science, these guidelines can help design the L&D unit of the future. Design thinking methodology can be implemented at various stages of healthcare building projects and during retrofits of existing facilities. One way to employ a human-centered approach toward improving healthcare design would be to create a national database that could house examples of design that are both successes and failures. The clinical significance of heterogeneity of space but homogeneity of equipment cannot be determined from this study.

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Project 4b: Delayed Cord Clamping Cart (DCCC)

Abstract

Purpose: We sought to a) study the usability and acceptability of the delayed cord clamping cart (DCCC), which provides a safe surface for HCPs to simultaneously perform neonatal resuscitation and delayed cord clamping after delivery and b) assess the cart’s impact on clinical and team performance via testing in a simulated setting and during cesarean sections.

Scope: Delaying cord clamping (DCC) for at least 60 seconds after delivery is a practice recommended by the World Health Organization (WHO). However, DCC can also delay indicated interventions in neonates requiring resuscitation at birth. To address this issue we designed a cart that enables HCPs to initiate resuscitation during DCC.

Methods: The DCCC was designed, refined and tested during simulated deliveries and then used during 17 low-risk full-term cesarean sections while an investigator observed and recorded its usage and effectiveness. Following the delivery HCPs were debriefed on their experience. Patients and their partners were also surveyed 12-24 hours postpartum.

Results: The DCCC can be safely and effectively implemented to allow DCC during low-risk, full-term cesarean sections. Some unforeseen additional benefits of the cart included clarifying work spaces among HCPs and mitigating fears of hypothermia by providing a dry surface for the neonate.

Key words: delayed cord clamping, neonatal resuscitation, iterative design, csections

Report

Purpose: We sought to study the usability and acceptability of this cart. Our secondary objective is to evaluation its impact on clinical and team performance via testing in simulations and during cesarean sections.

Scope: DCC for at least 60 seconds after delivery is a practice recommended by WHO. Benefits for pre-term neonates include, but are not limited to, reductions in inotropic support, blood transfusions, and intraventricular hemorrhage.^{1,2} However, preterm neonates are more likely to present with apnea and bradycardia and require positive pressure ventilation (PPV) and other resuscitative interventions at birth, necessitating their rapid transfer to a surface that facilitates such procedures, typically a bed that provides radiant heat, oxygen, other necessary supplies, and equipment. DCC delays transfer to such a bed, so the birth of a non-vigorous neonate mandates immediate cord clamping and transfer. Because the need for resuscitation is more common in preterm neonates (the population in whom DCC provides documented benefits) a method for allowing simultaneous DCC and resuscitation is indicated. To address this issue we designed a delayed cord clamping cart (DCCC) that can be positioned near to the mother on which the neonate can be placed while allowing simultaneous DCC and resuscitation (warming, drying, stimulation, PPV, etc.).

Methods: This observational study was approved by the Stanford University IRB. The study unfolded in two phases. The first phase involved use of the DCCC during simulated deliveries at [The Center For Advanced Pediatric and Perinatal Education](#) (CAPE) at Stanford by the HCPs and engineers on our research team. Usability

data was compiled via face-to-face interviews and review of recorded simulated deliveries. The second phase of the study was carried out in the delivery rooms of Packard Children's Hospital Stanford. Informed written consent was obtained from 17 pregnant patients at term scheduled for a non-emergent cesarean section. An investigator observed and recorded the use of the DCCC and its effectiveness in facilitating DCC during cesarean section. Immediately following each delivery, the HCPs were debriefed on their experience using the cart. Patients and their partners were also given a short survey 12 – 24 hours postpartum regarding their experience with the cart.

Results: Usability data compiled during the first phase of the study via face-to-face interviews and review of recorded simulated deliveries was used in the iterative design process to refine the DCCC for subsequent trials. In the second phase of the study, approximately 20 hours of observation during cesarean section and discussion during debriefings of HCPs was performed. The recorded debriefings of the clinicians were transcribed and analyzed for patterns. Patient surveys were analyzed to identify patient concerns including perceived safety issues. Recurring themes from the analysis were identified and utilized during the iterative design process. The DCCC provides a flat surface for delayed cord clamping and does not endanger the sterility of the operative field nor interfere with delivery or resuscitation of the neonate based on subjective feedback from the HCPs and objective analysis of recorded simulated deliveries. Some unforeseen additional benefits of the cart included clarifying workspaces among HCPs and mitigating fears of hypothermia by providing a dry surface for the neonate. The next step in this process is to conduct testing in the preterm population. A collaboration has been established with Anup Katheria, M.D., at Sharp Mary Birch Hospital in San Diego, California, to use the DCCC during the birth of preterm neonates in 2020.

Conclusion: The DCCC can be safely and effectively incorporated into the workflow of obstetric and neonatal teams to allow DCC during low-risk, full-term cesarean sections. Use in the preterm population will be assessed in 2020. Patients do not perceive use of the DCCC in a negative manner. Our surveys reflect that the cart fulfilled the requirements of clinicians and had some additional benefits we did not foresee such as: 1) Delineating the pediatrician's and obstetrician's space to do their clinical tasks more easily and 2) Removing fears about hypothermia during delayed cord clamping since the baby is completely removed from the fluids while delaying cord clamping.

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Project 4c: Pelvic Lift Cushion (PLC)

Abstract

Purpose: We sought to design and test a novel device (PLC) that improves patient and physician comfort during pelvic exams when ob-gyn beds are not available.

Scope: Since many emergency rooms and antepartum units are not equipped with the type of beds needed to conduct pelvic exams, HCPs must improvise (e.g., placing an inverted plastic bedpan under a patient's pelvis); however such improvisation causes patient discomfort and creates waste.

Methods: We performed a qualitative study comparing a novel device, the PLC, to the current standard, a bedpan, during pelvic exams in the emergency room and antepartum units when an ob-gyn bed is not available. Device assignment was randomized. Following the exam, HCPs completed a usability assessment and patients were surveyed regarding their experience.

Results: Data collection is ongoing. The PLC may represent an affordable and effective alternative to an inverted bedpan during pelvic exams in settings where ob-gyn beds are not available.

Key words: Pelvic exam, patient-centered designed, obstetrics, gynecology

Report

Purpose: We sought to design and test a PLC for its ability to improve patient and physician comfort during pelvic exams.

Scope: Because the emergency department (ED) and antepartum unit (APU) are not typically equipped for pelvic exams, HCPs improvise by placing an inverted plastic bedpan underneath the patient's pelvis to achieve the dorsal lithotomy position. This causes patient discomfort creates disposable waste. Another work-around commonly used is a rolled towel placed under the pelvis. These options often fail to allow the visibility necessary for an appropriate exam. A reusable PLC is needed to improve patient comfort, enable proper visualization of anatomical structures and decrease waste.

Methods: This study was approved by the Institutional Review Board at Stanford University. Subjects are female patients over 18 years of age recruited from the patient population of the Stanford ED and APU and represent a diverse range of racial/ethnic backgrounds. This is a qualitative study comparing a novel device, the pelvic lift cushion, to the current standard, a bedpan, during pelvic exams in the ED and APU when an ob-gyn bed is not available. The PLC is made from waterproof closed-cell foam and is covered with a protective disposable water-resistant shield that prevents it from directly touching a patient. Its primary functions are to provide the patient with comfort during pelvic exams and to lift the pelvic floor for the HCP to perform a pelvic exam with ease. The angle of the cushion creates space for a clinician to easily use a speculum and create maximum visibility. Device assignment is randomized. We plan to conduct at least 25 exams with the PLC and 25 with the bedpan for a total of 100 surveys. Following each exam, HCPs complete a usability assessment and patients are surveyed regarding their experience. HCPs are queried on their years of experience, whether or not the PLC made it easier for them to conduct different types of pelvic exams and whether or not the cushion improved visibility of the pelvic floor. Patients are surveyed regarding their overall satisfaction, comfort level and perceived safety and are also asked to provide feedback on how to improve the PLC. Similar questions are asked of the HCPs and patients who use the bedpan.

Results: Data collection is ongoing in the Stanford University Hospital ED and APU. We plan to extend the study to low resource clinics in India and Africa. Preliminary feedback indicates that the PLC is an affordable and effective solution in settings where ob-gyn beds are not available.

Conclusion: Thoughtfully designed medical products can improve the safety and efficacy of care while also enhancing patient comfort and satisfaction. The PLC may represent an affordable and effective alternative to an inverted bedpan during pelvic exams.

LIST OF PUBLICATIONS AND PRODUCTS

Oral Presentations:

- 1) Sherman J. Challenges performing delayed cord clamping & CPAP resuscitation for pre-term infants during C-section or vaginal delivery. Oral presentation presented at: International Symposium on Human Factors and Ergonomics in Health Care: Shaping the Future; 2016 April; San Diego, CA.
- 2) Lyndon A. Parent perspectives on safety in neonatal and maternity care. Oral presentation presented at: International Forum on Quality and Safety in Healthcare; 2017 April; London, England.
- 3) Yurashevich M, Fedoruk K, Austin N, Lee HC, Lipman SS, Riley ET. An analysis of labor room usage and cesarean section rates on high volume, high acuity obstetric unit: does layout matter? Oral presentation presented at: American Society of Anesthesiologists Annual Meeting; 2017 October; Boston, MA.

- 4) Kowalczyk J, Lipman SS, Carvalho B. Estimating obstetric anesthesiology workload: number of deliveries versus workload hours per hour. Oral presentation presented at: American Society of Anesthesiologists Annual Meeting; 2017 October; Boston, MA.
- 5) Fuerch J, Halamek L, Bitan Y, Harris S, Karn K, Ilan R. Information display in the intensive care unit – considerations for system design and implementation. Oral presentation presented at: International Symposium on Human Factors and Ergonomics in Health; 2017 March; New Orleans, LA.
- 6) Sherman J, Lee HC, Weiss M, Kristensen-Cabrera A. Medical device design education: identifying problems through observation and hands-on training. Oral presentation presented at: Stanford Medicine X ED; 2018 April; Palo Alto, CA.
- 7) Fuerch J, Kristensen-Cabrera A, Lee HC, Halamek L. Optimizing technical performance through gaze pattern categorization during simulated neonatal resuscitation. Oral presentation presented at: International Pediatric Simulation Symposia and Workshops; 2018 May; Amsterdam, Netherlands.
- 8) Umoren R. Gaps in Neonatal Provider Performance on standardized simulations: a report from the NRP eSim Study. Oral presentation presented at: American Academy of Pediatrics (AAP) National Conference & Exhibition; 2019 October; New Orleans, LA.
- 9) Umoren R. Pre-course preparation with eSim computer-based simulation improves neonatal provider performance on standardized simulations. Oral presentation presented at: American Academy of Pediatrics (AAP) National Conference & Exhibition; 2019 October; New Orleans, LA.

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- 1) Hamilton C, Sie L, Lipman SS, Halamek L, Daniels K, Lee CH. Finding opportunities to foster effective and efficient communication in labor and delivery using simulation. Poster presented at: Agency for Healthcare Research and Quality Research Conference; 2015 October; Crystal City, VA.
- 2) Lipman SS. Impact of the Electronic Medical record on nurse's time allocation during cesarean delivery. Poster presented at: American College of Obstetricians and Gynecologists Annual Clinical and Scientific Meeting; 2016 May; Washington, DC.
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- 4) McDonald A, Schwandt D, Sherman J, Austin N, Carvalho B, Lee HC, Lipman SS. Labor units of the future: physical design and standardization of labor and delivery suites. Poster presented at: Society for Obstetric Anesthesia and Perinatology Annual Meeting; 2016 May; Boston, MA.
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- 6) Kumar P, Lee HC, Bergin J. Non-contact vital sign monitor for the NICU. Poster presented at: Pediatric Academic Societies Annual Meeting; 2017 May; San Francisco, CA.
- 7) Yurashevich M, Fedoruk K, Austin N, Lee H, Lipman S, Riley E. An analysis of labor room usage and cesarean section rates on high volume, high acuity obstetric unit: does layout matter?. Poster presented at: Society for Obstetric Anesthesia and Perinatology Annual Meeting; 2017 May; Bellevue, WA.
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- 1) Fuerch JH. Utilizing human factors to redesign the neonatal intensive care unit. Workshop presented at: International Symposium on Human Factors and Ergonomics in Health Care: Shaping the Future; 2016 April; San Diego, CA.

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